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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,066	12/04/2001	Tasuku Honjo	Q67573	3829

7590 05/06/2003

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/000,066

Applicant(s)

HONJO ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. copy in 09/529064.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I and species election of SEQ ID NO: 7 in Paper No. 6 is acknowledged. Claims 1-20 are pending in this application. Claims 3-9 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1, 2, and 10 are under examination as they pertain to SEQ ID NO: 7.

Priority

2. Applicant's priority claim to 09/529064, PCT JP98/04515, and Japanese application 9-27463 is acknowledged. However, because no utility for the claimed protein is disclosed in the priority applications (see below) the priority granted is the filing date of the instant application, 4 December 2001.

Claim Objections

3. Claim 10 is objected to because it depends in part from a non-elected claim. Claims 1 and 2 contain a typographical error: "comprising" should read --comprises--.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 2, and 10 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148

U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The specification fails to provide objective evidence of any activity for the protein. Further, the specification does not disclose any activities, diseases or conditions known to be associated with the protein. The utilities identified by the applicant on pages 14-24 are not specific or substantial. While applicant lists a number of possible general uses for the protein, the specification does not disclose any diseases or conditions known to be associated with or affected by it. Merely listing a number of possibilities is not sufficient to identify or confirm a "real world" context of use; clearly further research would be required to identify a disease in which the protein is involved. Thus, further research is required to identify a disease for which it could be used, or a disease for which its presence would be diagnostic. Further, identification of a receptor for this protein, and screens for molecules that affect this protein, are useful only in research to determine the function of the protein itself: there is no "specific benefit in currently available form" to be derived from such studies. Applicant thus does not identify or confirm a "real world" context of use; clearly further research would be required to identify a disease or function associated with this protein and thus endow it with a utility. See *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is

therefore not a license to experiment. See also the Revised Interim Utility Guidelines available at www.uspto.gov.

The claimed invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Applicant does not identify any other proteins to which this protein is related that might potentially identify a function for it, nor or any other properties that might endow it with a utility disclosed. There is therefore no specific, substantial, or credible utility that is well known, apparent, or implied by the disclosure of any properties of the protein in the specification; no such properties are disclosed.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1,2, and 10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 1 and 10 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for a polypeptides comprising SEQ ID NO: 7, would still not reasonably provide enablement for homologues of the protein, including sequences comprising

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fragments of the protein. No biological function, activity, or essential properties of the protein of SEQ ID NO: 7 are defined in the specification. Since the biological activity of this parent protein is therefore not defined, one of skill in the art would not be able to make homologues of the protein possessing this biological activity. The amino acid sequence of a polypeptide determines its structural and functional properties, and predictability of which amino acids can be substituted is extremely complex and well outside the realm of routine experimentation, because accurate predictions of a polypeptide's structure from mere sequence data are limited. Since detailed information regarding the structural and functional requirements of the protein are lacking, it is unpredictable as to which other proteins, if any, meet the limitations of the claims. Therefore it would require undue experimentation by one of skill in the art to practice the invention as claimed without further guidance from the instant specification.

9. Claims 1 and 10 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus, i.e the protein of SEQ ID NO: 7 and homologues of this protein. The other sequences disclosed are related to SEQ ID NO: 7 only by the method used to identify them; there is no indication that they are linked by structure or function to SEQ ID NO: 7 and there is thus no indication that they are members of the genus of proteins that are structurally and functionally related to SEQ ID NO: 7. Thus Applicant has disclosed one species of the claimed genus, the protein of SEQ ID NO: 7, but has not disclosed sufficient species to describe the broad genus of any protein homologous to it having the identifying characteristics of the parent protein.

The instant disclosure of a single species of protein does not adequately describe the scope of the claimed genus, which potentially encompasses proteins of very different sequence. A description of a genus may be achieved by means of a recitation of a representative number of members of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of proteins. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from other proteins with different functions are missing from the disclosure. Thus, no identifying characteristics or properties of the instant protein is provided such that one of skill would be able to predictably identify other molecules encompassed by the claims as being identical to that instantly disclosed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NO:7 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

10. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for the protein of SEQ ID NO: 7 or homologues thereof, would still not reasonably provide enablement for pharmaceutical compositions. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The designation "pharmaceutical composition" indicates that there is a therapeutic use for the protein. As stated above, Applicant has provided no guidance as to which, if any, diseases or conditions the protein could be used to treat. Thus, it would require undue experimentation for one of skill in the art to use the protein as a therapeutic agent.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are drawn to homologues of the disclosed protein. While a general description of such homologues is presented on p. 5, there is no definition that would serve to indicate which proteins would be considered to be homologues and which would not be.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 2, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimazu et al., J. Exp. Med. 1999, vol. 189(11), pp. 1777-1782.

Shimazu et al. disclose a protein, MD-2, that is identical to Applicant's SEQ ID NO: 7. See figure 1 and attached sequence alignment. Because priority is granted only to filing date of the instant application for the reasons set forth in paragraph 2 above, the teachings of Shimazu et al. are prior art under 35 U.S.C. 102(b).

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Janet Andres, Ph.D.

May 5, 2003